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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,920	02/20/2002	James R. Uhl	07039-393001	2201

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EXAMINER	
CROSS, LATOYA I	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,920	UHL ET AL.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2004 has been entered. Claims 1-8 are pending.

Withdrawal of Rejections from Previous Office Action

- The obviousness rejections over Aldeen in view of Eberle and Aldeen in view of Eberle and Moore, Jr. are withdrawn in view of Applicants' amendment to recite the presence of a single aperture in the bottom of the inner containment vessel.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 4, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,335,673 to Goldstein et al.

Goldstein et al teach a device for collecting saliva samples. The device

comprises an inner containment vessel (15) having a single aperture (20) at its bottom. The device further comprises an outer containment vessel (12), a collection swab (3) and swab diluent (22) present in the inner containment vessel. In use, a sample is collected on the pad end (3) of the swab. The swab is inserted into the inner containment vessel (15) and contacts the diluent (22) to preserve the sample present on the swab. A cap is placed on the vessel. When the time comes to analyze the sample, the complete assembly (swab inside of inner containment vessel which is inside of the outer containment vessel) is centrifuged whereby the part of the sample to be tested flows down through the aperture (20) and into the bottom of the outer containment vessel. See figures 5 and 6, col. 8, lines 7-25. As a part of a kit, Goldstein et al teach combining the swab, inner container (15), cap (18), swab diluent (22) and centrifuge tube (12). Packaging material would be inherent to the kit since the components of the kit would necessarily have to be packed in some form to transport.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102 in view of the teachings of Goldstein et al.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goldstein et al.

Goldstein et al teach a method for collecting saliva samples. The method uses a device comprising an inner containment vessel (15) having a single aperture (20) at its bottom. The device further comprises an outer containment vessel (12), a collection swab (3) and swab diluent (22) present in the inner containment vessel. In use, a sample is collected on the pad end (3) of the swab. The swab is inserted into the inner containment vessel (15) and contacts the diluent (22) to preserve the sample present on the swab. A cap is placed on the vessel.

When the time comes to analyze the sample, the complete assembly (swab inside of inner containment vessel which is inside of the outer containment vessel) is centrifuged whereby the part of the sample to be tested flows down through the aperture (20) and into the bottom of the outer containment vessel. Goldstein et al teach that hepatitis A/B and syphilis may be detected using method. See col. 8, lines 7-25. Viruses such as hepatitis A/B and syphilis may be considered "microorganisms" if given the dictionary definition of "an organism of microscopic size". However, in the alternative, if the viruses disclosed by Goldstein et al are not microorganisms, it would have been obvious to one of ordinary skill in the art to detect microorganisms since microorganisms are known for causing disease in humans and animals. Thus, to prevent diseases caused by microorganisms, it would have been obvious to one of ordinary skill in the art to detect microorganism using the method Goldstein et al, whereby a sample suspected of containing microorganisms is collected on a swab, disposed into an inner containment vessel and centrifuged to collect the sample in an outer centrifuge tube.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 2, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of US Patent 5,882,943 to Aldeen.

The disclosure of Goldstein et al is described above. While Goldstein et al teach detecting microorganisms such as hepatitis A/B and syphilis, there is no disclosure of the microorganisms recited in claim 3 being detected. Further, there is no disclosure of packaging material indicating the use of the kit.

Aldeen discloses a kit and method for processing microorganisms (parasites) from human and animal specimens. The kit comprises a filtration apparatus and preservation fluid dispenser. Referring to figure 2, the filtration apparatus comprises a specimen receptacle (110) and a collection receptacle (150). The specimen receptacle holds an original human or animal sample. Aldeen discloses detecting bacterium such as *E. coli* in the human or animal sample. it would have been obvious to one of ordinary skill in the art to use the method and device of Goldstein et al to detect common bacterium known for causing disease in humans and animals. The kit and method of Golstein et al are less invasive than collecting samples using syringes, yet they provide an easy means for obtaining a sample large enough for testing. With respect to the packaging material indicating the use of the kit, labels for packages conventionally have information regarding the reliability of the products and the purposes for which the product should be used. It would have been obvious to one of ordinary skill in the art to incorporate such information on the package material for the kit of Goldstein et al to inform the consumer of the purposes for which the kit may be used.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,498,395 to Moore, Jr. et al.

The disclosure of Goldstein et al is described above. Goldstein et al fail to teach using sterile containment vessels.

Moore, Jr. et al teaches the importance using a sterile centrifuge tubes for human samples. Sterile tube prevent the possibility of the sample being contaminated prior to testing. It would have been obvious to one of ordinary skill in the art to use sterile centrifuge tubes in

Golstein et al to alleviate the possibility of contaminating the sample itself and prevent false positives from resulting due to contaminants being present.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden
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